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A Look Into The New Diabetes Criteria

Diabetes Mellitus, a metabolic disorder of hyperglycemia affecting over 16 million people in the U.S., can result in long-term complications if not diagnosed and properly treated early. Diagnostic criteria were originally set in 1985 by the World Health Organization (WHO), using the oral glucose tolerance test along with a fasting plasma glucose (FBS) to confirm diagnosis. In 1997, the American Diabetes Association (ADA) determined that only a FBS was necessary to make a diagnosis. The purpose of this study was to compare interpretations of the FBS values of subjects using the WHO and ADA criteria. Thirty participants, from 35-65 years of age, were required to fast for at least an 8 hour period and then have a FBS sample drawn. The resulting data was compared to both the WHO and ADA diagnostic criteria in order to determine if an underestimation of diagnosis would occur using only the FBS specimen as required by the new ADA criteria. Out of the 30 samples, 28 were considered normal by both classifications, 1 was considered to have an impaired fasting glucose by both, and 1 was considered to be diabetic by both. The observed data showed complete agreement between the WHO and ADA criteria. Follow-up studies using larger population sizes should be performed before sole reliance on the ADA guidelines is adopted.

Jenny Kinsley

A Look Into The New Diabetes Criteria

Diabetes Mellitus is a diverse collection of metabolic disorders with different etiologies and clinical pictures. One characteristic common to all types of this disease is hyperglycemia (increased blood glucose). This condition occurs as a result of insulin deficiency, either from defects in insulin secretion or insulin action (1). Diabetes can be divided into three major types. Type 1 diabetes results from pancreatic beta-cell destruction or a defect in beta-cell function. This type is more commonly diagnosed in children than adults. Patients with Type 1 are reliant on insulin injections for life (2). Type 2 diabetes occurs in patients that have insulin resistance or an underproduction of insulin. The majority of patients with Type 2 are diagnosed during adulthood. This type is the most common form of diabetes (2). The third and final type of diabetes is Gestational diabetes. Occurring during pregnancy, the glucose intolerance usually returns to normal after delivery (2).

Diabetes is a very serious condition with many symptoms and long-term complications. Symptoms of hyperglycemia include polyuria (increased urination), polydipsia (increased thirst), weight loss, and blurred vision (1). The long term complications are the most life-threatening to diabetics. Chronic hyperglycemia can be associated with damage, dysfunction, and failure of organs such as the eyes, kidneys, nerves, heart and blood vessels (1). These complications can include retinopathy with potential loss of vision, nephropathy leading to renal (kidney) failure, and risk of foot ulcers and amputation.

In the United States, over 16 million people, 6% of the population, are estimated to have diabetes. As many as 50% of these people are undiagnosed. Diabetes is currently the fourth leading cause of death by disease in our country. Demographics also indicate that diagnosis of diabetes is steadily increasing (3). The majority of diabetics in the U.S. are over 45 years of age. It is estimated that by 2030, 70 million adults will be 65 years of age or older. With this population increasing, the diagnosis of diabetes will also be on the rise (3). It is vitally important that the undiagnosed population attain a diagnosis of diabetes before the disease course becomes life-threatening.

In 1979, the National Diabetes Data Group (NDDG) published a diagnosis scheme to be used in the diagnosis of diabetes. This classification was based on the knowledge of diabetes at that time. It incorporated a combination of clinical manifestations and treatment requirements (1). In 1980, the World Health Organization (WHO) performed a study, and later endorsed the recommendations of the NDDG. Both groups recognized two major types of diabetes: insulin

dependent diabetes mellitus (IDDM) and non-insulin dependent diabetes mellitus (NIDDM). Three other types of diabetes were also included: gestational diabetes mellitus (GDM), malnutrition-related diabetes, and other types (1). Patients were categorized based on the results obtained from a fasting plasma glucose and a two hour oral glucose tolerance test (OGTT). The results of the fasting plasma glucose could be divided into three categories:

- ≥ 140 mg/dl – diagnostic for diabetes mellitus
- 126-140 mg/dl – impaired glucose tolerance
- <126 mg/dl – normal

Similarly, the OGTT results could conclude diabetes mellitus if the fasting value was ≥140 mg/dl and 2-hour value was ≥200 mg/dl. Impaired glucose tolerance was found if the fasting glucose was <140 mg/dl and the 2-hour value was 140-199 mg/dl (4). Until 1995, this classification scheme was upheld in clinical practice.

In 1995, the American Diabetes Association (ADA) formed a committee to review scientific literature since 1979 and determine if changes in the classification and diagnosis of diabetes were necessary (1). The expert committee of the ADA did indeed determine a necessity for new diagnostic criteria. The main purpose of the criteria was "to move away from a therapeutically oriented criteria to one based on disease etiology when possible providing a classification that reflects the etiology and/or pathogenesis of diabetes and guidelines for the diagnosis of disease" (5). The classification system was renamed with four categories: Type 1 (IDDM), Type 2 (NIDDM), gestational diabetes, and other. One significant difference in the diagnostic criteria was the removal of the OGTT. The committee determined that oral glucose tolerance testing was not advocated for clinical purposes. The committee then assumed that the simplicity of obtaining a fasting plasma glucose would be used by more physicians, and therefore result in detection of a greater proportion of patients with undiagnosed diabetes (6). Therefore, the new criteria for fasting plasma glucose were lowered and categorized as:

- ≥ 126 mg/dl – provisional diagnosis of diabetes
- 110-126 mg/dl – impaired fasting glucose
- < 110 mg/dl – normal

A result of provisional diagnosis of diabetes was to be confirmed with a second fasting glucose on a subsequent day (1). Although many doctors still rely on the old criteria, in 1997 the revisions made by the ADA were put into effect internationally.

The aim of this research study was to compare the criteria from the 1980 WHO and 1997 ADA diagnostic criteria in the diagnosis of diabetes. Type 2 diabetes was specifically studied due to the commonality of the disease and the increasing adult and elderly populations in the United States.

RESEARCH DESIGN AND METHODS

The subject group for this study consisted of 30 people ranging from 35-65 years of age. An announcement looking for volunteers to have a fasting blood glucose drawn was posted within the laboratory at St. Anthony's Medical Center in Rockford, IL. Any person within the age group was eligible to volunteer to participate in the study. Outpatients coming to the laboratory for blood draws were also asked to participate if they fell within the age range. Before accepting the volunteer into the study, each person was asked of diabetic status. Anyone already diagnosed with diabetes was disqualified from participation. All other participants were accepted, as long as each appeared in generally good health.

Each volunteer was required to fast for at least 8 hours before blood drawing occurred. One to two glasses of water was allowed during the fasting period. Laboratory employees were then to have a fasting blood glucose sample drawn by any other laboratory employee proficient at normal venipuncture techniques. Outpatients, already fasting for other blood draws, were to have one extra tube of blood drawn specifically for the study. Blood from each participant was drawn in the amount of 5cc into a sodium heparin vacutainer tube. After acquiring the blood, each sample was immediately centrifuged. Following centrifugation, the plasma was removed from the cells and transferred into another tube. The plasma was then refrigerated until testing was performed.

Blood samples were collected over the course of a two-week period. At the end of each week (on Saturday), the weeks worth of samples were tested. Testing was performed on the Beckman Astra 4 instrument. This instrument uses the glucose oxidase reaction method. During this reaction, oxygen is consumed at the same rate as glucose reacts with the enzyme glucose oxidase to form gluconic acid. During all times, the rate of oxygen consumption is directly proportional to the concentration of glucose within the sample (4).

RESULTS

At the conclusion of all testing, the data was compiled. Each result was compared first to the WHO criteria and next to the ADA criteria. Every piece of data was categorized as shown in Table 1. Out of 30 participants, 28 were found to be normal by both the WHO and ADA criteria, one was found to have impaired fasting glucose (IFG) by both criteria, and one final person was found to be diabetic by both criteria. A comparison using both the ADA and WHO criteria showed the same results: 93.3% of the sample population was considered normal, 3.3% have IFG, and 3.3% were to be diabetic.

TABLE 1

1985 WHO Criteria	1997 ADA Criteria			
	NORMAL	IFG	DIABETES	TOTAL
NORMAL	28	0	0	28
IFG	0	1	0	1
DIABETES	0	0	1	1
TOTAL	28	1	1	30

CONCLUSIONS

The results of this study do not show a significant difference in the use of the ADA criteria versus the WHO criteria for the diagnosis of diabetes. In fact, no difference is seen between the two methods at all. However, the data found do fit the estimate that 6% of the U.S. population is considered diabetic (3.3% IFG + 3.3% diabetic), with 50% of those people currently undiagnosed (3.3% IFG) (3). It should be mentioned that due to the sample size, the accuracy of this data may not be very good. A larger sample size may have shown more variation in results and a different conclusion may have been found for this study.

Although it was once believed that the ADA criteria would revolutionize the diagnosis of diabetes, making it more efficient and cost effective, many studies have shown otherwise. For example, a study published in September 1998 comparing the WHO and ADA classification in older adults found significantly different results. According to this study, the estimates of diabetes prevalence based on the WHO classification were two to four times higher than found with the ADA criteria. This was found to be due to an increased sensitivity of the 2-hour glucose tolerance test, which is used in the WHO classification. The study stated that the fasting blood glucose alone would be most appropriate for epidemiological studies (7). Similarly, another study performed by Gomez-Perez et. al. found that 82% of the WHO IFG cases were classified as normal by the ADA system of classification. They concluded that compared with WHO criteria, ADA fasting criteria significantly underestimates the prevalence of untreated diabetes in the population (5).

The proposal of the ADA using only the fasting plasma glucose was based on the simplicity and practicality of the method. It was to be used to detect a prediabetic state, in order to reduce the mortality and morbidity of the disease as it progresses. It was to be assumed that the IFG was to identify persons at risk for developing diabetes. However, most of the studies testing this theory have not found this to be true. Although closer to the realization of this hypothesis, another study performed within the Japanese-Brazilian population still found

differences between the criteria. Fewer people were classified as having diabetes or being predisposed for the disease using the ADA criteria (6).

All of the studies presented used a population size of at least 1000 participants. Each study also came to basically the same conclusion. The results of this study, although they do not defend the use of the ADA criteria, they do not relinquish its use either. The data derived from the sample population do not match others from the aforementioned studies. This could be due to the size of the sample population used. Although alone this study cannot form any solid conclusions, it can be used with others to begin to determine whether the sole use of the ADA criteria is a reliable and effective move to make within the medical field.

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